IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ETHICON WAVE 1 CASES LISTED IN EXHIBIT A**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' REPLY TO DEFENDANTS RESPONSE IN OPPOSITION TO PLAINTIFFS' *DAUBERT* MOTION TO EXCLUDE, OR IN THE ALTERNATIVE, TO LIMIT THE OPINIONS AND TESTIMONY OF STEVEN MACLEAN, PH.D., P.E..

Defendants' have failed to adequately refute the fact that:

1) Defendants' own 30(b)(6) witness, Dr. Thomas Barbolt admitted that Ethicon's Prolene mesh devices undergo *in vivo* surface degradation – binding the Defendants to this opinion which is inconsistent with the unreliable opinions offered by Steven MacLean, Ph.D., P.E.;

2) Steven MacLean, Ph.D., P.E.'s molecular weight opinions that are based on Ethicon's Seven-Year Dog Study are unreliable;

3) Dr. MacLean's cross-sectional schematic and opinions on theoretical total molecular weight are unreliable;

4) Dr. MacLean's is unqualified to offer pathology opinions; and

5) Dr. MacLean's histology/pathology experiments are unreliable.

Having failed to refute the critical points advanced in Plaintiffs' motion to exclude Dr. MacLean, this Court should grant Plaintiffs' motion and exclude Dr. MacLean's opinions and testimony as set forth below[1] and in greater detail in Plaintiffs' Memorandum in Support of

[1] Plaintiffs have determined that not every response offered by the Defendants warrants a reply and stand by all of the arguments addressed in their Memorandum in Support of Plaintiffs' Motion to Exclude the Opinions and Testimony of Defendant Ethicon and Johnson & Johnson's Expert Steven MacLean, Ph.D., P.E. (ECF No. 2206) (hereinafter referred to as "Ptfs' Motion"). Plaintiffs' decision to not reply to some of the Defendants' arguments contained with Defendants' Response (ECF No. 2287) (hereinafter "Defs' Response") should not be construed as a

Plaintiffs' Motion to Exclude the Opinions and Testimony of Defendant Ethicon, Inc. and Johnson & Johnson's Expert Steven MacLean, Ph.D., P.E. (ECF No. 2206) (hereinafter referred to as "Plfs' Motion").

ARGUMENT

I. The Defendants Have Already Admitted Under Oath Through Their 30(b)(6) corporate witness, Dr. Thomas Barbolt, that the Prolene used to manufacture their SUI and POP mesh products undergoes *in vivo* degradation.

The litigation against Ethicon and Johnson & Johnson concerning their Prolene-based stress urinary incontinence (SUI) and pelvic organ prolapse (POP) products has been ongoing for several years. During this time period, many of the Defendants' employees were deposed, including witnesses designated by the Defendants as 30(b)(6) witnesses most knowledgeable about certain subject matters, including the subject of *in vivo* Prolene degradation, who were required under the Federal Rules of Civil Procedure – including in particular FRCP Rule 30(b)(6) – to provide complete, knowledgeable and binding testimony on behalf of Ethicon and Johnson & Johnson:

> The testimony elicited at the Rule 30(b)(6) deposition represents the knowledge of the corporation, not of the individual deponents. The designated witness is 'speaking for the corporation'.... The corporation appears vicariously through its designee. If the persons designated by the corporation do not possess personal knowledge of the matters set out in the deposition notice, the corporation is obligated to prepare the designees so that they may give knowledgeable and binding answers for the corporation.

Spicer v. Universal Forest Products, E. Div., Inc., No. 7:07CV462, 2008 WL 4455854, at *4 (W.D. Va. Oct. 1, 2008) (quoting United States v. Taylor, 166 F.R.D. 356 (M.D.N.C. 1996).

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waiver or withdrawal of any arguments contained within Ptfs' Motion.

In accordance with the requirements of Rule 30(b)(6), the Defendants designated Dr. Thomas Barbolt as its 30(b)(6) corporate designee on the subject of Prolene's ability to degrade *in vivo*. Contrary to the Defendants' argument, Dr. Barbolt unequivocally testified numerous times throughout his deposition that Prolene does undergo *in vivo* surface degradation and that Ethicon knew this several years prior to disseminating misinformation to physicians in its labeling which erroneously claimed that the Prolene does not undergo *in vivo* degradation.

The Defendants' argument that "not only does Dr. Barbolt's testimony not support Plaintiffs' theory that PROLENE degrades, but the testimony rebuts their assertion" is unbelievable, wholly misrepresents the Defendants sworn testimony provided by its 30(b)(6) corporate designee and is borderline frivolous. Dr. Barbolt's testified that:

Q: Is it Ethicon's position that the antioxidants in the polypropylene Prolene fibers in TVT can leach from the fibers?

A: THE WITNESS: Yes.[2]

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Q. And could you explain to the ladies and gentlemen of the jury what we mean by "leach"?

A. Leaching means the movement of substances from an implant into the surrounding tissue.[3]

****

Q. So you would agree as a spokesperson - - as a 30(b)(6) person for Ethicon that the surface of polymer fibers, including the polypropylene fibers in TVT, can crack?

A. Yes.[4]

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[2]Exhibit AA - Excerpt from the 30(b)(6) Deposition of Dr. Thomas Barbolt, 1/8/2014, at 360:20-25.
[3]Exhibit AA - Excerpt from Barbolt Dep., 1/8/2014, at 361:2-6.
[4]Exhibit AA - Excerpt from Barbolt Dep., 1/8/2014, at 385:14-20.

Q. Despite the antioxidants being added to the Prolene sutures, in two of the Prolene sutures in the study, the surface layer was cracked, correct?

A. Two revealed cracking, yes.

Q. **And you aren't suggesting to the ladies and gentlemen of the jury that those cracks were anything other than the Prolene polypropylene, are you**?

A. **No, I am not suggesting that**, and that's not reflected in this report.

Q. **You would agree that the surface that's cracked here is the polypropylene surface layer, correct**?

A. In reading the report, it says that – **that's what I would conclude**.[5]

****

Q. **And that's Ethicon's position as you -- as the spokesperson for Ethicon, it's Ethicon's position that degradation, surface degradation, can occur, correct**?

A. **Yes**.

Q. And this was known well in advance of this statement that the material is not absorbed, nor is it subject to degradation, correct?

A. Yes. This is from 1992.[6]

Thus, Ethicon and Johnson & Johnson are bound by the admissions of its 30(b)(6) corporate designee that their Prolene-based SUI and POP mesh products undergo *in vivo* surface degradation. Nevertheless, the Defendants hired Dr. MacLean in an effort to undo this damaging testimony and, not surprisingly, Dr. MacLean's opinions contradict Dr. Barbolt's testimony. The Defendants should not be permitted to undo testimony of its 30(b)(6) corporate designee simply because they do not like the answers he provided. Courts have refused to allow these types of substantive changes even by errata: "To allow these types of corrections would undermine the Rule 30(b)(6) deposition. An interpretation of liberal—indeed unlimited—amendments and

[5]Exhibit AA - Excerpt from Barbolt Dep., 1/8/2014, at 396:2-23 (emphasis added).
[6]Exhibit AA - Excerpt from Barbolt Dep., 1/8/2014, at 409:2-13 (emphasis added).

corrections would discourage the careful preparation of 30(b)(6) witnesses. Rather than advancing the pursuit of truth in discovery, a policy of liberal "amendments" and "corrections" would encourage and intensify lawyer wordsmithing and parsing." *Wyeth v. Lupin Ltd.*, 252 F.R.D. 295, 297 (D. Md. 2008).

Other district courts have reached similarly conclusions. In *Rainey v. American Forest & Paper Ass'n. Inc.*, 26 F. Supp.2d 82, 94 (D.D.C. 1998), the Defendants' designated 30(b)(6) witnesses whose binding testimony failed to create a material issue in dispute. Thus, the plaintiff moved for summary judgment. In response, the Defendants attached an affidavit of a former employee which contradicted the defendant's corporate designees' sworn testimony. Like here, the plaintiff in *Rainey* argued that Rule 30(b)(6) precluded the defendant from developing a new theory of the facts that differs from that articulated by the designated representative. The District Court agreed, precluded the contrary evidence and held that:

> Plaintiff's theory is consistent with both the letter and spirit of Rule 30(b)(6). First, the Rule states plainly that persons designated as corporate representatives "shall testify as to matters known or reasonably available to the organization." Fed.R.Civ.P. 30(b)(6). This makes clear that a designee is not simply testifying about matters within his or her own personal knowledge, but rather is "speaking for the corporation" about matters to which the corporation has reasonable access. *United States v. Taylor,* 166 F.R.D. 356, 361 (M.D.N.C.1996), *aff'd United States v. Taylor,* 166 F.R.D. 367 (M.D.N.C.1996) (quoting 8A Charles Alan Wright *et al.,* Federal Practice and Procedure, § 2103, at 36–37 (2d ed.1994)). By commissioning the designee as the voice of the corporation, the Rule obligates a corporate party "to prepare its designee to be able to give binding answers" in its behalf. *Ierardi v. Lorillard, Inc.,* 1991 WL 158911, at *3 (E.D.Pa. Aug.13, 1991); *Taylor,* 166 F.R.D. at 361 (designee "presents the corporation's 'position' on the topic") (internal citation omitted). **Unless it can prove that the information was not known or was inaccessible, a corporation cannot later proffer new or different allegations that could have been made at the time of the 30(b)(6) deposition.** *See Ierardi,* 1991 WL 158911, at *3; *Taylor,* 166 F.R.D. at 362.

Id at 94 (emphasis added). This is exactly what the Defendants are attempting to do with Dr. MacLean whose opinions concerning Prolene's propensity to degrade wholly contradicts the binding testimony of Ethicon's corporate representative, Dr. Thomas Barbolt. For this reason

alone, Dr. MacLean's opinions should be excluded.

II. Dr. MacLean's Opinions Regarding the Seven-Year Dog Study Are Unreliable.

Defendants argue that Dr. MacLean's reliance on the molecular weight data from Ethicon's Seven-Year Dog study which was derived from comparing an explanted PROLENE 5/0 suture implanted in 1985 to a PROLENE 4/0 suture in 1992 was proper. *See* Defs' Response at p. 7. In support, Defendants cite to portions of Dr. MacLean's deposition testimony where he opines, without any factual or meaningful scientific basis other than his say-so, that the molecular weight of a Prolene 4-0, 5-0, 6-0 are essentially the same. Defs' Response at 7-8.

However, Dr. MacLean's say-so does not demonstrate reliability. Dr. MacLean has not even attempted to verify these opinions and the evidence demonstrates the opposite. For example, according to Ethicon's internal documents, Prolene 6-0 suture has a molecular weight of 358,000 and a molecular number of 83,000. The Prolene 4-0 suture used as the control by Ethicon in 1992 in its Seven-Year Dog Study has a different molecular weight and a different molecular number (324,000/60,000). *See* Exhibit BB- Internal Ethicon Laboratory Notebook, (DEPO.ETH.MESH.00005605). Based on Ethicon's own internal documents, the molecular weight of these differently sized Prolene sutures varies significantly – contrary to Dr. MacLean's opinions that the molecular weight of Ethicon's different Prolene sutures are essentially the same regardless of their size. Having failed to demonstrate that the explanted 1985 Prolene 5-0 suture shares the same molecular weight as the 1992 Prolene 4-0 suture used as a control, Dr. MacLean's reliance on the Seven-Year Dog Study amounts to nothing more than speculation and guesswork, which should be excluded as unreliable. See e.g., *Smith v. Virginia Commonwealth Univ.*, 84 F.3d 672 (4th Cir.1996) (en banc)("[A]n expert's opinion is inadmissible when it is based on assumptions that are speculative and are not supported by the record."); *Rosen v.*

Chiba-Geigy Corp., 78 F.3d 316, 318-19 (7th Cir. 1996) (stating that "the courtroom is not the place for scientific guesswork, even of the inspired sort").

III. Dr. MacLean's Cross-Sectional Schematic and Molecular Weight Calculations Are Unreliable

The Defendants argue that Dr. MacLean's calculations of molecular weight derived from the data generated by Plaintiffs' experts are reliable. However, it is clear from Dr. MacLean's own report that he is cherry picking data to come to a calculation that supports his opinion. In his general expert report, Dr. MacLean writes "[a]ccording to Ethicon's documents, the depth of microcracks in explanted PROLENE sutures has been measured to be 0.5 – 4.5 microns." *See* MacLean Expert Report at p. 77 (Exhibit C to Plfs' Motion) (citing ETH.MESH.12831405). Indeed, other internal Ethicon documents, the crack depths are measured between 0.7 to 1.3 microns. *See* Exhibit L to Plf's Motion - ETH.MESH.12831405. Yet, Dr. MacLean assumes the depths of the cracks in the Dog Study are 4 microns. The reason he does this is obvious: he knows that a crack depth somewhere below 4 microns invalidates his calculations:

> Q. So if you assume 4 microns, it gets you outside of the standard deviation for the molecular weight?
>
> A. At 4 microns, it does, correct.
>
> Q. At 2 microns, it gets you closer to the bulk analysis, which would wash out the molecular weight changes on the surface, they'd be masked by the bulk?
>
> A. It could. Yeah, at some smaller crust thickness, you would be within the statistical confines of the original data.

MacLean Dep., 9/29/15, at 278:23-279:8 (Exhibit B to Plfs' Motion).

Dr. MacLean should not be permitted to cherry-pick data from various different studies, different test subjects, with varying measurements in order to get to a result that supports his opinions especially where other internal Ethicon documents describe smaller crack depths which

Dr. MacLean disregards. As the Fourth Circuit has held: "Courts have consistently excluded expert testimony that "cherry-picks" relevant data." *E.E.O.C. v. Freeman*, 778 F.3d 463, 469-70 (4th Cir. 2015) (citing *Bricklayers & Trowel Trades Int'l Pension Fund v. Credit Suisse Secs. (USA) L.L.C,* 752 F.3d 82, 92 (1st Cir.2014); *Greater New Orleans Fair Hous. Action Ctr. v. U.S. Dep't of Hous. & Urban Dev.*, 639 F.3d 1078, 1086 (D.C.Cir.2011); *Barber v. United Airlines, Inc.*, 17 Fed.Appx. 433, 437 (7th Cir.2001); *Fail–Safe, LLC v. A.O. Smith Corp.,* 744 F.Supp.2d 870, 891 (E.D.Wis.2010); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 524 F.Supp.2d 1166, 1176–77 (N.D.Cal.2007). Such methods are unreliable because "'[c]herry-picking' data is essentially the converse of omitting it: just as omitting data might distort the result by overlooking unfavorable data, cherry-picking data produces a misleadingly favorable result by looking only to "good" outcomes." *Id.*

Dr. MacLean's opinions based on his cherry-picked data should be excluded as unreliable.

IV. Dr. MacLean is Unqualified to Offer His Unreliable Pathology/Microtome Opinions and His Pathology Experiments Are Unreliable.

As an initial matter, the Defendants argue that Dr. MacLean is not offering pathology opinions even though he provides opinions related to (1) artifacts caused by microtome processing; (2) Hematoxylin and Eosin (H&E) histology staining; and (3) artifacts related to histology and polarized light microscopy. Defendants do not dispute that H&E staining and microtoming are methods employed by pathologist. Instead they argue that "[w]hile a pathologist may use microtoming, microscopy, and staining in their analysis, the application of these tools is not limited to pathologists." Defs' Response at 10-11. Defendants' then make the bold assertion that "Dr. MacLean is more than qualified" but cite to no testimony or other evidence to support these unsupported conclusory statements. As federal district courts

throughout the United States have acknowledged: "[A] bold statement of the experts' qualifications, conclusions, and assurances of reliability are not enough to satisfy the *Daubert* standard." *Doe 2 v. Ortho-Clinical Diag., Inc.*, 440 F. Supp. 2d 465, 471 (W.D.N.C. 2006) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 43 F. 3d 1311, 1315-1316 (9th Cir. 1995), 43 F.3d at 1318) (*Daubert II*)).

Moreover, even if Dr. MacLean was qualified to offer opinions concerning these pathology methods, his opinions are unreliable and do not fit the facts of the case. For example, Dr. MacLean infers in his Expert Report and Supplemental Expert Reports that Dr. Iakovlev's opinion concerning the degraded bark layer that Dr. Iakovlev has observed during his histopathological analysis of Ethicon's explanted Prolene-based devices might be artifact caused when the specimens are sliced by the microtome and processed onto slides or artifact caused by polarized light microscopy. *See* MacLean Expert Report at p. 40 (Exhibit C to Plfs' Motion) and MacLean Supplemental Report at pp. 28-31 (Exhibit D to Plfs' Motion). However, Dr. MacLean testified that to offer opinions that Dr. Iakovlev is misinterpreting artifact as a degraded layer of polypropylene, Dr. MacLean would have to "see that specimen first-hand to be able to make that assessment" which he has not done in this case. *See* MacLean Dep., 4/18/16 at 117:6-9 (Exhibit V to Plfs' Motion).

Dr. MacLean further testified:

Q. And here you are -- I think what you're doing is you're attempting to demonstrate what you believe the -- it's your opinion that the cracked outer layer that is identified by Dr. Iakovlev is artifact from polarized light microscopy?

A. Oh, no. Not necessarily. It's -- this is just a caution and a warning that when you use polarized lighting, that you can get some degree of shading and some -- and varying degrees of illumination, and you just need to be aware of those artifacts as you interpret the results.

Q. **Are you going to offer any opinion at trial that any of the photo -- or the**

microphotographs that you've looked at that were taken by Dr. Iakovlev were caused by polarizing artifact?

A. **I don't know. I'd have to go back and look at his universe of images. All I'm saying here is that when you use polarized light, you just need to be careful, because you could introduce things that just truly aren't there. That's -- that's all I'm saying.**

Q. **…. sitting here right now, do you have any opinion that any of the microphotographs that were taken from -- by Dr. Iakovlev and are in his expert report are actually depicting some sort of polarizing artifact?**

A. I can say this: That there may be polarizing artifacts in his images.

See MacLean Dep., 4/18/2016, at 109: 11-110: 25 (Exhibit V to Plfs' Motion) (emphases added).

Thus, not only is Dr. MacLean unqualified to offer these pathology opinions or opinions concerning artifacts caused by microtome processing or polarized light but these opinions are based on unreliable speculation, unsupported by the facts and will only mislead the jury who may improperly conclude that Dr. Iakovlev's degradation findings were caused by some type of microtome or polarized light microscopy artifact that even Dr. MacLean admitted he could conclude. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 137, 118 S. Ct. 512, 515, 139 L. Ed. 2d 508 (1997) ("Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert"); *Weisgram v. Marley Co.*, 169 F.3d 514, 519-520 (8th Cir. 1999) (finding reversible error where the trial court allowed expert witness to testify based on "rank speculation"); *Smith v. Virginia Commonwealth Univ.*, 84 F.3d 672 (4th Cir.1996) (en banc)("[A]n expert's opinion is inadmissible when it is based on assumptions that are speculative and are not supported by the record."). Dr. MacLean is not qualified to offer these opinions and, even if he were, his opinions are speculative, misleading and would not assist the trier of fact. As such, Dr. MacLean's pathology and microtome opinions should be excluded.

V. Dr. MacLean's Histology Experiments Are Unreliable.

The Defendants offer various excuses to address the reliability concerns raised by Plaintiffs in their Motion to exclude Dr. MacLean's histology experiment, including Plaintiffs' arguments that Histion and/or Dr. MacLean manipulated the data by discarding 46 paraffin- and resin-embedded slides and by deviating from Dr. MacLean's histology staining and processing protocol established prior to commencing his histology experiment. The Defendants argue that these 46 paraffin and resin-embedded slides were rejected because the paraffin- and resin-embedded rabbit skin tissue control failed quality control, independent and without considering the test slides (the slides containing Prolene specimens) not as a result of selection bias or data manipulation. *See* Defs' Response at p. 18 and Exhibit P to Defs' Response at p. 4.

However, Histion's own lab notebook contradicts this argument and demonstrates that on March 12, 2016, each of the 22 individual paraffin-embedded test specimens that were rejected by Mr. Simon failed quality control (denoted by an "X" in the QC column next to each individual slide). *See* Histion Lab Notebook at p. 12 (Exhibit Z to Plfs' Motion). On the same page, Mr. Simon's handwritten notes also state that "**All slides** failed QC – due to overstaining [with] Eosin". *Id*. Nowhere in Histion's notebook does it suggest that only the control rabbit skin tissue failed quality control, despite Defendants' arguments to the contrary.

Likewise, on March 14, 2016, Histion's technician placed an "S" in the quality control column next to **each** of the individual resin-embedded specimens that Mr. Simon rejected after he determined these specimens "failed quality control" due to "stain quality". *Id* at p. 8. Mr. Simon's handwritten notes again demonstrate that each of these specimens were evaluated by Mr. Simon who determined that each of the 24 resin-embedded test slides stained too dark: "Technovit plastic surrounding **specimens** stained too dark [with] eosin." *Id*. The Histion lab

notebook strongly suggests that Mr. Simon did in fact inspect each of the paraffin- and resin-embedded test slides before determining that that **all** 46 slides either stained too dark or overstained resulting in the slides being rejected and which led Mr. Simon to deviate from his pre-study protocol.

More concerning than this, however, is that the Defendants' have not attached any microphotographs of these 46 rejected test slides as exhibits to their Response, have not produced microphotograph images of these 46 rejected test slides and have not offered to make these 46 rejected test slides available for physical inspection by Plaintiffs' experts, strongly suggesting that Mr. Simon and/or Dr. MacLean disposed of these 46 rejected slides. As a consequence, the Plaintiffs' experts cannot analyze these rejected slides to independently verify that the Prolene in these 46 paraffin- and resin-embedded slides did not trap the H&E histology stains or that the subsequent deviations from Dr. MacLean's protocol caused the slides that were accepted and relied upon by Dr. MacLean to be insufficient stained as a result of excessive washing or failure to adequately remove the paraffin and/or wax in which these samples were embedded. Accordingly, Dr. MacLean experiment is unreliable and should be excluded.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court grant their Motion to Exclude the Opinions and Testimony of Dr. Maclean, Ph.D., P.E.

Dated: June 8, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 8, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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